

8 THE LACK OF ONTOLOGICAL AWARENESS IN EVIDENCE-BASED MEDICINE ALLOWS OVERDIAGNOSIS

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Objectives A problem with the approach of Evidence-based Medicine (EBM) is the current ability to only reduce but not prevent overdiagnosis. Overdiagnosis is broadly defined as ‘making people patients unnecessarily, by identifying problems that were never going to cause harm or by medicalising ordinary life experiences through expanded definitions of diseases’. One aspect of overdiagnosis is *overdefinition*, such as lowering the threshold for treatment for a risk factor. A current example is the UK’s National Institute for Health and Care Excellence (NICE) updated draft guidance for the diagnosis and management of hypertension in adults. The recommendations in the guidance are not evidence based and will increase overdiagnosis. However, EBM would be insufficient to avoid overdiagnosis even if this NICE guidance followed the principles. The objective of this study is to show why EBM is insufficient to avoid over diagnosis.

Method This study analyse the NICE draft guidance by the principles of following EBM guidance: Users’ Guides to the Medical Literature by (Guyatt et al), Guidance for modifying the definition of diseases: A checklist (Doust et al), and EBM manifesto for better healthcare (Heneghan et al). The principles of these analyses are what the consequences would have been *if* the NICE guidance had followed these principles. The principles and consequences are then analysed for their epistemological and ontological properties to determine what kind of scientific theory that leads the current EBM.

Results EBM do not sufficiently assess the ontological aspect of a diagnosis. In the case of the NICE guidance, the ontological status of hypertension is primarily as a risk factor. A risk factor of such is a continuum with no clear boundary between normal (health risk small enough to be accepted) and pathological (health risk unacceptably high). Therefore, the diagnosis of hypertension is subject to the problematic *sorites paradox*. The original puzzle, from 400 BCE, is: how many times can we remove grains from a heap before we no longer have a heap? In this case, when a risk factor is accepted as a disease, how low a risk is low enough *not* to be a disease? EBM does not assess this problem. Instead, the present EBM is dominated by an epistemological approach, which legitimise any risk to become a disease, followed by the consequence of overdiagnosis.

Conclusions Due to lack of ontological awareness and epistemological dominance, the current EBM approach does not sufficiently address overdiagnosis. Increase awareness of ontological aspects is necessary. The NICE guidance for hypertension provides a good basis for a much-needed discussion about what possible ontological solutions could bring us closer to limiting overdiagnosis via EBM.

Oral Presentations

1 USE OF THE MODIFIED EARLY WARNING SCORE (MEWS) TO PREDICT MICU READMISSION

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Objectives Medical complications that result in patient readmissions to the intensive care unit (ICU) are known to be associated with increased mortality and length of stay. Scoring systems have been used in healthcare systems for decades to objectively assess a patient’s current status and implement the appropriate interventions based on the score generated from physiologic variables that comprise each scoring system. The Modified Early Warning Score (MEWS) employs five physiologic parameters (systolic blood pressure, heart rate, respiratory rate, temperature, and level of consciousness) for scoring and has been an essential tool for the identification of deteriorating patients. The early identification of a deteriorating patient is essential to decrease ICU readmission, length of stay, and mortality. The purpose of this study was to determine if there is any association between the MEWS and medical intensive care unit (MICU) readmission within 72 hours of initial discharge.

Method This was a retrospective study that used patient data spanning a 40-day period from September to November 2016. After ethics board approval, we reviewed the electronic health records (EHR) of 50 adult patients admitted to and subsequently discharged from the medical intensive care unit (MICU) of an urban academic medical center located in the Midwestern United States. We manually extracted patient demographic data including patient age, gender, weight, height, and the admitting diagnosis. Clinical variables collected include the value of each parameter of the MEWS as well as the MEWS score calculated from physiologic data entered into the EHR twelve hours, six hours, and one hour prior to MICU readmission. Additionally, Acute Physiologic Assessment and Chronic Health Evaluation II (APACHE II) score was calculated for each patient. The extracted data was recorded in REDCap, a web-based HIPAA compliant research database.

Results

Results The median MEWS score calculated from physiologic data entered into the electronic health record (EHR) twelve and six hours prior to MICU readmission was 3.0 for patients readmitted to the ICU compared with a median MEWS score of 2.0 for their cohorts who were not readmitted. The median MEWS score one hour before MICU readmission for subjects readmitted to the MICU was 4.0 compared to a median MEWS score of 2.0 for their cohorts who were not readmitted to the MICU during that one-hour period. Mann-Whitney U test revealed that there was a significant association ($P = 0.013$) between MICU readmission and the MEWS score calculated one hour before ICU readmission. Additionally, logistic regression analysis showed that this MEWS score predicts MICU readmission (OR 1.8, 95% CI 1.14 to 2.72).

Conclusions The MEWS independently predicts the likelihood of MICU readmission. Since the MEWS score can be automatically generated by the EHR it is prudent for clinicians to use it for frequent monitoring of patients during the first 72 hours of their discharge from the intensive care unit.

2 RETHINKING BIAS AND TRUTH IN EBM

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Objectives Abstract In modern philosophy, the concept of truth has been problematized from different angles, yet in evidence-based health care (EBHC), it continues to operate hidden and almost undisputed through the linked concept of 'bias.' To prevent unwarranted relativism and make better inferences in clinical practice, clinicians may benefit from a closer analysis of existing assumptions about truth, validity, and reality. Here we give a brief overview of several important theories of truth, notably the ideal limit theorem (which assumes an ultimate and absolute truth towards which scientific inquiry progresses), the dominant way truth is conceptualized in the discourse and practice of EBHC.

Method We draw on Belgian philosopher Isabelle Stengers' work to demonstrate that bias means one thing if one assumes a world of hard facts 'out there,' waiting to be collected. It means something different if one takes a critical view of the knowledge-power complex in research trials. Bias appears to have both an unproductive aspect and a productive aspect as argued by Stengers and others: Facts are not absolute but result from an interest, or *interesse*: a bias towards a certain line of questioning that cannot be eliminated.

Results The duality that Stengers' view invokes draws attention to and challenges the assumptions underlying the ideal limit theory of truth in several ways. Most importantly, it casts doubt on the ideal limit theory as it applies to the single case scenario of the clinical encounter, the cornerstone of EBHC. To the extent that the goal of EBHC is to support inferencing in the clinical encounter, then the ideal limit as the sole concept of truth appears to be conceptually insufficient.

Conclusions We contend that EBHC could usefully incorporate a more pluralist understanding of truth and bias and provide an example how this would work out in a clinical scenario.

3 DON'T LABEL AGEING AS DISEASE: THE KIDNEY AGE COMMUNICATION TOOL

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Objectives Previous research shows that the terminology 'chronic kidney disease' (CKD) is problematic for both patients and general practitioners, arguably because it represents an ageing process rather than a disease. We have previously proposed an alternative terminology 'kidney age' to supersede the terminology of CKD stages 2, 3a, 3b and 4. We aim to develop a communication tool that can be used to discuss declining kidney function with patients without using the terminology of 'disease'.

Method We used electronic health record data from UK primary care to design a prototype communication aid: a table and explanatory text showing how eGFR values map to bands of 'kidney age', and the increasing CVD risk at each band of kidney age. The design and content were refined iteratively in consultation with patient-public involvement representatives. UK general practitioners were then interviewed about the proposed design and content.

Results Interviews are ongoing but results to date suggest that GPs would welcome 'kidney age' terminology and our communication tool, possibly modified, as a potential intervention. **Conclusions** A web-based version of the communication aid is currently under development, that can be tested as an intervention in a future parallel-group trial.

4 THE SECTION ON MATERIALS AND METHODS IN PUBLISHED REPORTS OF RANDOMIZED CONTROLLED TRIALS (RCTS) DOES NOT PROVIDE SUFFICIENT INFORMATION TO ALLOW CLINICAL REPLICABILITY OF COMPLEX INTERVENTIONS: A COCHRANE REHABILITATION METHODOLOGICAL PAPER

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Objectives To study if Randomized Controlled Trials (RCTs) on complex interventions published in top journals include all the practical details needed to replicate the intervention in everyday clinical practice (clinical replicability). We chose rehabilitation as a case-study because the World Health Organization calls for its development within health services, and due to its intrinsic complexities.

Method Online survey of a pre-defined sample of clinical expert teams from different world regions with diverse rehabilitation competences. Forty-seven clinicians from 7 Physical and Rehabilitation Medicine (PRM) teams (Belgium, Italy, Malaysia, Pakistan, Poland, Puerto Rico, USA), including 20 physicians, 12 physiotherapists, 6 occupational therapists, 6 psychologists and 3 others. The team leaders were active researchers. All RCTs published between January and July 2017 in the top PRM journals (76 RCTs) were reviewed by each team leader. 14 questions developed using CONSORT and TIDieR checklists through consensus and piloting.

Results The response rate was 99%. Inter-rater agreement was moderate/good. All participants considered unanimously 12 (16%) RCTs clinically replicable and none not replicable. Of the other, 56 (74%) RCTs have been considered replicable and 45 (59%) not replicable by at least one complete team. At least one 'absent' information was found by all participants in 60 RCTs (79%), and by a minimum of 85% in the remaining 16 (21%). Information considered to be less well described (8-19% 'perfect' information) included two providers (skills, experience) and two delivery (cautions, relationships) items. The best described (50-79% 'perfect') were the classic methodological items included in CONSORT (descending